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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,430	09/22/2003	Paul D. Rubin	4821-523	6519

20582 7590 08/25/2005

JONES DAY
51 Louisiana Aveue, N.W
WASHINGTON, DC 20001-2113

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,430	RUBIN ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21-34 is/are pending in the application.

4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 21-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/22/03.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 08/17/05.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment and Information Disclosure Statement filed 09/22/03.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: fluoxetine or the R or S isomer thereof, norcisapride or the (+) or (-) stereoisomer thereof, ubidecarenone, dipyramole, pilocarpine or a stereoisomer thereof, primidone or the R or S stereoisomer thereof, or orphenadrine citrate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ricardo Moran on 08/17/05 a provisional election was made without traverse to prosecute the invention of fluoxetine, claim 28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Young US 5,712,302.

Young discloses a composition comprising optically pure R(+) ondansetron or salt thereof, substantially free of its S(-) stereoisomer (see abstract and claim 1). Salt thereof, includes hydrochloride (column 9, lines 24-34, and claim 2). Optically pure R(+) ondansetron contains at least 99% by weight of R(+) ondansetron, and 1% or less of S(-) ondansetron (column 7, lines 48-58). The amount of R(+) ondansetron ranges from 0.001 mg to 35 mg (column 8, lines 52-54). The composition further comprises pharmaceutically acceptable carrier, and other therapeutic agents (column 9, lines 16-24; and column 10, lines 7-24). Young further teaches the composition is suitable for oral or parenteral administration (column 9, lines 9-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson WO 92/00103, in view of Young US 5,712,302.

Johnson teaches a pharmaceutical composition comprising combination of a 5-HT_3 receptor antagonist, a 5-HT reuptake inhibitor, and a pharmaceutical acceptable carrier (page 1, lines 15-19; page 2, lines 31 through page 3, lines 1-9; and claims 1&2). Johnson further teaches 5-HT_3 receptor antagonist includes ondansetron, and 5-HT reuptake inhibitor includes fluoxetine (page 1, line 32; page 2, lines 6-10; claim 7). The composition can be administered orally or parenterally (page 4, lines 14-24).

Johnson does not expressly teach the 5-HT_3 receptor antagonist comprises the claimed ondansetron.

Young teaches ondansetron is a safe and competitive antagonist 5-HT_3 receptor antagonist (column 2, lines 60-67). Young further teaches the use of optically pure R(+) ondansetron or salt thereof, substantially free of its S(-) stereoisomer for the treatment of diseases, while decreasing the usual adverse effects (column 5, lines 61-67). Young also teaches a composition comprising optically pure R(+) ondansetron or salt thereof, substantially free of its S(-) stereoisomer (see abstract and claim 1). Salt thereof, includes hydrochloride (column 9, lines 24-34, and claim 2). Optically pure R(+) ondansetron contains at least 99% by weight of R(+) ondansetron, and 1% or less of S(-) ondansetron (column 7, lines 48-58). The amount of R(+) ondansetron ranges from 0.001 mg to 35 mg (column 8, lines 52-54). The composition further comprises pharmaceutically acceptable carrier, and other therapeutic agents (column 9, lines 16-24; and column 10, lines 7-24). Young further teaches the composition is suitable for

oral or parenteral administration (column 9, lines 9-15). Thus, it would have been obvious to one of ordinary skill in the art to modify the 5-HT_3 receptor antagonist of Johnson using the optically pure R(+) ondansetron or salt thereof, substantially free of its S(-) stereoisomer in view of the teaching of Young, because Young teaches the use of optically pure R(+) ondansetron or salt thereof, substantially free of its S(-) stereoisomer for the treatment of behavioral disorders such as mood anxiety and schizophrenia, while decreasing the usual adverse effects (column 5, lines 61-67; and column 6, lines 1-5), and because Johnson teaches the combination of 5-HT_3 receptor antagonist, and 5-HT reuptake inhibitor for the treatment of depression and/or migraine (page 2, lines 19-20; and page 6, lines 33-36).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Radulovacki et al. is cited as of interest for the teaching of combination of agents that possess serotonin-related pharmacological activity.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Examiner
Art Unit 1615